IOMED

MAR 3 1 2006

K060236

SUMMARY OF SAFETY AND EFFECTIVENESS
Iontophoresis Electrode
Date of Summary: 27 January 2006

A. General Provisions

Submitter's Name:	IOMED, Inc.
Submitter's Address:	2441 South 3850 West, Suite A Salt Lake City, UT 84120-9941
Contact Person:	Curtis Jensen Director, Quality and Regulatory
Classification Name:	Iontophoresis Device 21 CFR 890.5525
Proprietary Name:	MW-1000 Iontophoretic Drug Delivery Electrode
Common Name:	Iontophoresis Drug Delivery Electrode

B. Name of Predicate Device(s)

- Iontophoresis Device:K932621
  Iontophoresis Drug Delivery Electrode
  IOMED, Inc. RH-801/GS Iontophoretic Drug Delivery Electrode
- Iontophoresis Device: K042590
  Iontophoresis Drug Delivery System
  Mattioli Engineering Transderm Ionto System, MK 2

C. Device Description

An iontophoresis device is a device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes. Iontophoresis technology is based on the principle that an electric potential will cause ions in solution to migrate according to their electrical charges. The quantity and distribution of a drug delivered into and across the skin by iontophoresis is dependent on the charge and molecular weight of the ion, the strength of the electrical current applied, electrode composition, duration of current flow, and numerous other factors.

The IOMED, Inc. MW-1000 iontophoresis system consists of an active delivery electrode and a return electrode. The electrodes are designed for a single-patient, one-application use and should be used with IOMED's approved iontophoretic dose controller. The active delivery electrode is attached to a handle which is used to guide the device over the area to be treated. The handle is designed to be reused.

The IOMED, Inc. MW-1000 iontophoresis system is designed to attach to IOMED's approved Phoresor®. These devices provide control of the current and therefore dosage delivered.

D. Intended Use

Iontophoretic drug delivery electrodes are indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injections. They are also indicated for iontophoretic dermal administration of IONTOCAINE® (Lidocaine HCl 2% and Epinephrine 1:100,000 Topical Solution).

E. Drug Delivery and Biocompatibility

Drug Delivery

Drug delivery rate measurements of both negatively and positively charged drugs were performed *in vitro* in freshly excised hairless mouse skin using the method described by Petelenz et. Al., *J Controlled Release* 20 (1992), 55-56. Commercial formulations of dexamethasone sodium phosphate (0.4% w/v dexamethasone phosphate equivalent) and lidocaine hydrochloride (4% w/v) were used as model drugs for cathodal (-) and anodal (+) iontophoresis, respectively. Drugs quantization in the skin and receptor solution was performed by radioassay using 3H-dexamethasone sodium phosphate and 14C-lidocaine hydrochloride tracers. The MW-1000 drug electrode is identical to that used for the RH-801/GS with the exception of the skin fixation material. This difference will not affect the results of this testing.

This testing shows that both negatively and positively charged drugs can be effectively delivered using the drug electrode to be used with the MW-1000.

Safety and Biocompatibility

Primary dermal irritation studies were carried out in rabbits in accordance with FDA regulations for Good Laboratory Practices using Dexamethasone sodium phosphate and lidocaine hydrochloride as model compounds. Using standard Primary Dermal Irritation Index scores of 0.0 (non-irritant), 0.1 – 2.0 (mild irritant), 2.1 – 5.9 (moderate irritant), and 6.0 and greater (severe irritant), the RH-801/GS was rated as a mild irritant (0.5) during lidocaine administration, a non-irritant during a Dexamethasone administration from a Dexamethasone/lidocaine (1:2) mixture, and a non-irritant during Dexamethasone administration alone.

This testing was done as part of the RH-801/GS 510(k) (K932621). The materials used in the MW-1000 drug electrode are identical to those used for the RH-801/GS with the exception of the skin fixation material. This difference will not affect the results of this testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2006

IOMED, Inc
c/o Mr. Curtis Jensen
Director, Quality and Regulatory
2441 South 3850 West, Suite A
Salt Lake City, Utah 84120

Re: K060236
Trade/Device Name: MW - 1000 Iontophoretic Drug Delivery Electrode
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis device
Regulatory Class: III
Product Code: EGJ
Dated: January 27, 2006
Received: January 30, 2006

Dear Mr. Jensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act), as long as you comply with all of the Act's requirements relating to drugs labeled or promoted with the devices as described below. You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Our substantially equivalent decision does not apply to the drugs that you will label or promote for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs, nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland

As you are aware, iontophoresis devices that are intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis or for other uses, if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, were classified into Class II. An iontophoresis device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes other than those specified for class II devices is classified into Class III (21 CFR 890.5525). We published our strategy for calling for premarket approval (PMA) applications in the enclosed Federal Register, dated May 6, 1994, and the enclosed memorandum, dated April 19, 1994, and the enclosed Federal Register, dated August 22, 2000.

If you have any questions regarding this letter, you may contact:

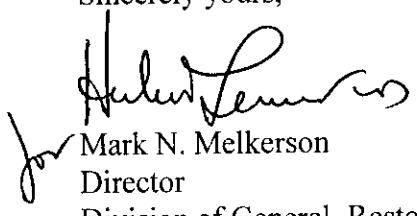
Kevin Lee, M.D.
Food and Drug Administration
Center for Devices and Radiological Health
Division of General, Restorative and Neurological Devices
9200 Corporate Boulevard (HFZ-410)
Rockville, Maryland 20850
(301) 594-1296

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by

reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

Applicant: Iomed, Inc.

510(k) Number (if known): _____

Device Name: MW-1000 Iontophoretic Drug Delivery Electrode

Indications For Use: Iontophoretic drug delivery electrodes are indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injections. They are also indicated for iontophoretic dermal administration of IONTOCAINE® (Lidocaine HCl 2% and Epinephrine 1:100,000 Topical Solution).

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060236

Prescription Use ✓ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)